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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,078	04/08/2004	Robert A. Davis	56630US007	1677

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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
07/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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Office Action Summary	Application No.	Applicant(s)	
	10/821,078	DAVIS ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 58-96 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 58-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dischler (U.S. Patent No. 6,585,693) in view of Richter et al (U.S. Patent No. 3,396,419).

With respect to **Claims 58,64-67,69,70,73,74:** Dischler teaches a single-dose syringe 24 comprising cylindrical syringe body 62 (container) defining an interior volume, wherein said

container is comprised of at least one polymeric layer (wall) that does not contain metal lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. With regard to the limitation “at least one barrier layer that is substantially impermeable to ethylene oxide”, applicant sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and sets forth in claim 63 that the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene). Dischler teaches the same materials for the instant inner and outer barrier lamina, thus at least one of the inner and outer barrier lamina taught by Dischler is substantially impermeable to ethylene oxide.

Dischler teaches that the container is impermeable to ethylene oxide but does not teach that the container is provided with a sterile exterior by exposure to a sterilizing gas. Richter teaches that a process called "cold sterilization" whereby articles are sterilized with ethylene oxide is known (‘419, Col. 3, lines 30-33), and teaches that it is also known in the art to clean and sterilize (e.g. via autoclaving) an antiseptic composition dispenser, e.g. for surgical scrubbing, daily to prevent cross-contamination between the dispenser and its various users. (‘419, Col. 2, lines 22-26) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Dischler by providing the container with a sterile exterior by exposure to

ethylene oxide (sterilizing gas) as taught by Richter to properly sterilize and clean the dispenser to prevent cross-contamination of a user's skin and the dispenser. The device of the combined teaching of Dischler and Richter thus renders the limitation "wherein the container is provided with a sterile exterior by exposure to a sterilizing gas" obvious.

With respect to **Claim 62:** Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

With respect to **Claims 63,72,75:** Dischler teaches polypropylene and polyethylene as materials for the barrier layers, which are polyolefins.

With respect to **Claim 68:** Dischler teaches that the barrier lamina are flexible.

With respect to **Claim 71:** Dischler teaches that the polymer lamina are attached to one another via additional heat sealable polymer (heat activated adhesive) lamina therebetween that function also as barrier lamina.

With respect to **claim 76:** Dischler is silent regarding the percent of weight lost by the container based upon the weight of the skin composition. However, since the device of Dischler meets the claim limitations of claim 76 as to a composition and container made of identical materials to those disclosed by applicant, it would be obvious to one of ordinary skill in the art to modify the device of Dischler such that the container, packaged as to be shipped, will lose 2% or less by weight of the composition when placed in a convection oven at 60 degrees Celsius for 14 days with a reasonable expectation of success to prevent excess loss of composition upon use.

With respect to **claim 77:** Dischler is silent regarding a permeability to gaseous ethylene oxide. However, since Dischler discloses a container having an inner and outer layer made of identical materials to those disclosed by applicant for the respective claimed inner and outer layers, it would be obvious to one of ordinary skill in the art to modify the device of Dischler such that the container exhibits a permeability to gaseous ethylene oxide within the claimed range with a reasonable expectation of success to attain the proper minimal level of permeability to ethylene oxide to effect proper sterilization.

With respect to **Claim 81:** Dischler teaches a single-dose syringe 24 comprising cylindrical (i.e. tubular) syringe body 62 (container) defining an interior volume, wherein said container is comprised of at least one polymeric layer (wall) that does not contain metallic foil lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. With regard to the limitation “wherein the container exhibits permeability to gaseous ethylene oxide of 20 mg/hr/cm2 or less”, applicant sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and sets forth in claim 63 that the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene). Thus, while Dischler does not explicitly disclose a certain

permeability to gaseous ethylene oxide, since Dischler discloses a container having an inner and outer layer made of identical materials to those disclosed by applicant for the respective claimed inner and outer layers, it would be obvious to one of ordinary skill in the art to modify the device of Dischler such that the container exhibits a permeability to gaseous ethylene oxide within the claimed range with a reasonable expectation of success to attain the proper minimal level of permeability to ethylene oxide to effect proper sterilization.

Dischler teaches that the container is impermeable to ethylene oxide but does not teach that the container is provided with a sterile exterior by exposure to a sterilizing gas. Richter teaches that a process called "cold sterilization" whereby articles are sterilized with ethylene oxide is known (‘419, Col. 3, lines 30-33), and teaches that it is also known in the art to clean and sterilize (e.g. via autoclaving) an antiseptic composition dispenser, e.g. for surgical scrubbing, daily to prevent cross-contamination between the dispenser and its various users. (‘419, Col. 2, lines 22-26) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Dischler by providing the container with a sterile exterior by exposure to ethylene oxide (sterilizing gas) as taught by Richter to properly sterilize and clean the dispenser to prevent cross-contamination of a user's skin and the dispenser. The device of the combined teaching of Dischler and Richter thus renders the limitation "wherein the container is provided with a sterile exterior by exposure to a sterilizing gas" obvious.

With respect to **claim 83:** The one or more flexible walls free of metallic foil layers taught by Dischler comprise an inner layer facing the interior volume and an outer layer facing away from the interior volume. The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. With regard to the

limitation “wherein the container exhibits permeability to gaseous ethylene oxide of 20 mg/hr/cm2 or less”, applicant sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and sets forth in claim 63 that the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene). Thus, while Dischler does not explicitly disclose a certain permeability to gaseous ethylene oxide, since Dischler discloses a container having an inner and outer layer made of identical materials to those disclosed by applicant for the respective claimed inner and outer layers, it would be obvious to one of ordinary skill in the art to modify the device of Dischler such that the container exhibits a permeability to gaseous ethylene oxide within the claimed range with a reasonable expectation of success to attain the proper minimal level of permeability to ethylene oxide to effect proper sterilization.

With respect to **Claim 84:** Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

With respect to **Claim 85:** Dischler teaches polypropylene and polyethylene as materials for the barrier layers, which are polyolefins.

With respect to **claims 86-88:** Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 86) and a seal 50 (vent seal closing the vent orifice) and break zone 46 (dispensing seal).

With respect to **claim 89:** Dischler teaches a single-dose syringe 24 comprising cylindrical syringe body 62 (container) defining an interior volume, wherein said container is comprised of

at least one polymeric layer (wall) that does not contain metal lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. With regard to the limitation “at least one barrier layer that is substantially impermeable to ethylene oxide”, applicant sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and sets forth in claim 63 that the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene). Dischler teaches the same materials for the instant inner and outer barrier lamina, thus at least one of the inner and outer barrier lamina taught by Dischler is substantially impermeable to ethylene oxide. Dischler also teaches an applicator in the form of needle 32 that applies the medicament subcutaneously.

With respect to **Claim 91:** Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

With respect to **Claim 92:** Dischler teaches polypropylene and polyethylene as materials for the barrier layers, which are polyolefins.

With respect to **claims 93-96:** Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice) and a seal 50 (vent seal closing the vent orifice) and break zone 46 (dispensing seal).

With respect to **Claim 59:** Dischler teaches a syringe body 62 having walls comprised of polymeric lamina and therefore teaches that the barrier covers 100% (i.e. at least 60%) (claim 60) of the walls of body 62. Applicant has not established sufficient criticality for having a barrier material that covers less than 100%, therefore this limitation is considered an optimization of the surface area of said barrier layer(s). It would be obvious to one of ordinary skill in the art to modify the barrier coverage area to be less than 100% as the blister chambers collectively are not coextensive with said walls and therefore would only need the barrier functionality in the areas adjacent said chambers. Leaving the remainder free of barrier material would facilitate transparency and visual inspection of said syringe.

With respect to **Claims 61,79-81,82,90:** Dischler does not explicitly teach any of the items set forth in claims 61, 79-81, 82, 90, but does teach that second chamber 42 contains an injection prep or other sterilizing fluid, of which povidone (iodine complex) and chlorhexidine digluconate are examples that are well-known in the art, therefore it would be obvious to one of ordinary skill in the art to fill second chamber 42 with povidone with a reasonable expectation of success to accomplish the function of a skin antiseptic composition.

Double Patenting

4. All outstanding double patenting rejections are maintained herein.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761